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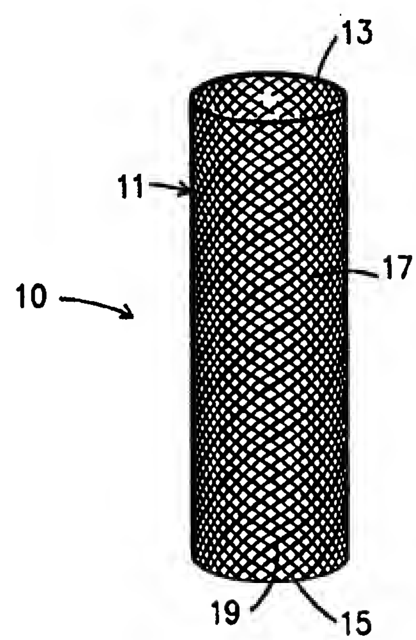
(54) Title: WIRE REINFORCED FABRIC STENT AND METHOD OF WEAVING

(57) Abstract

A stent (10) is made of a fabric knitted in a knitting machine (20). Knitting machine (20) receives a plurality of fabric strands (17) and at least one wire strand (19) from spools and knits them into a tubular fabric stent (11) having at least one reinforcing wire (19) interwoven in the fabric. If desired, the spool carrying the wire may rotate more slowly than the yarn spools so that the wire is braided about the yarn locking the yarn together. The wire may be made of materials such as Stainless Steel, Tungsten, Titanium, NITINOL, Gold or Silver.



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WIRE REINFORCED FABRIC STENT AND METHOD OF WEAVING

Technical Field

The present invention relates to a stent. More particularly, it relates to a wire reinforced fabric stent and method of weaving.

Background Art

In the prior art, stents are known to be made of interwoven groups of filaments and having a compliant outer covering positioned thereover. United States Patent 4,441,215 to Kaster discloses such a configuration. However, Kaster fails to teach or suggest a stent made of a compliant fabric having wire interwoven therewithin. Further, Kaster fails to teach or suggest a particular manner of weaving a stent as disclosed herein.

U.S. Patent 5,718,159 describes a stent having structural strands and three dimensionally braided textile strands integrated together to form a tubular shape. The metal structural strands are heat treated to impart a selected nominal shape in lieu of an original nominal shape. The present inventive process employs two dimensional braiding and there is no need to impart a selected nominal shape to the metal strands.

Applicant is also aware of United States Patent 5,562,725 to Schmitt et al. that discloses a radially self-expanding implantable intraluminal device wherein the stent is described as a tubular braid formed from two sets of yarns spiraling in opposing directions about a longitudinal axis of the tube being formed. Schmitt et al. fail to teach the particular interrelationship of reinforcing wire and yarn nor the specific method of weaving disclosed herein.

Disclosure of Invention

The present invention relates to a wire reinforced fabric stent and method of weaving. The present invention includes the following interrelated objects, aspects and features:

(1) In a first aspect, the inventive stent is made in a tubular shape woven on a knitting machine. The knitting machine is supplied with yarn from at least three separate spools of yarn and reinforcing wire from at least one spool of

wire. As the knitting machine receives the at least three strands of yarn and at least one strand of wire, a tubular stent is gradually formed.

(2) In the preferred embodiment, the reinforcing wire is supplied to the knitting machine at a slower speed than the speed at which the yarn from the other spools is supplied. If desired, a brake mechanism may be provided on the wire spool to prevent the wire from being freely supplied to the knitting machine.

(3) The resulting stent consists of a tubular fabric stent having at least one wire braided about the yarn, locking the yarn together and providing a stent with increased radial strength that can have its profile reduced for introduction into the body.

Accordingly, it is a first object of the present invention to provide a wire reinforced fabric stent and method of weaving.

It is a further object of the present invention to provide such a stent having an increased radial strength and reduced porosity than those in the prior art.

It is yet a further object of the present invention to provide such a stent wherein a knitting machine is supplied with yarn from at least three spools and wire from at least a fourth spool.

It is still a further object of the present invention to provide such a stent wherein the method of weaving the stent in a knitting machine includes the step of supplying wire at a slower speed than yarn.

These and other objects, aspects and features of the present invention will be better understood from the following detailed description of the preferred embodiment when read in conjunction with the appended drawing figures.

<u>Brief Description of Drawings</u>

Figure 1 shows a schematic representation of the use of a knitting machine supplied with yarn and wire to knit a tubular stent;

Figure 2 shows a schematic representation of the pattern of weaving of the fabric yarn and the reinforcing metal wire;

Figure 3 shows a side perspective view of a preferred finished stent depicting the configuration of reinforcing wires within the fabric weave;

Figure 4 shows a side perspective view of an alternate finished stent depicting the configuration of reinforcing wires within the fabric weave;

Figure 5 shows one embodiment of the present invention wherein the metal wire is woven into the fabric stent such that there is a separate metal layer followed by an integrally woven fabric-metal wire layer;

Figure 6 shows an alternate embodiment of the present invention wherein the metal wire is woven into the fabric stent such that there is a separate metal layer followed by a separate fabric layer;

Figure 7 shows a first step in one method of employing the stent of the present invention;

Figure 8 shows a second step in the one method of employing the stent of the present invention;

Figure 9 shows a first step in a second method of employing the stent of the present invention;

Figure 10 shows a second step in the second method of employing the stent of the present invention;

Figure 11 shows a first step in a third method of employing the stent of the present invention;

Figure 12 shows a second step in a third method of employing the stent of the present invention;

Figure 13 shows a side perspective view of an alternate finished stent depicting the configuration of one reinforcing wire within the fabric weave;

Figure 14 shows a side perspective view of an alternate finished stent depicting multiple reinforcing wires within the fabric weave in square-wave type patterns; and

Figure 15 shows a side perspective view of an alternate finished stent depicting multiple reinforcing wires within the fabric weave in coil-like patterns.

Best Mode for Carrying Out the Invention

With reference, first, to Figure 3, a stent in accordance with the teachings of the present invention is generally designated by the reference numeral 10 and is seen to include a tubular body 11 having generally circular open ends 13 and 15. Body 11 consists of a fabric weave preferably formed by a knitting machine and including fabric 17 as well as reinforcing wires 19 spiraling through fabric 17 as shown in Figure 3. Although the preferred stent of the present invention employs two or more reinforcing wire, stent 10 is not limited thereto and can be configured with one reinforcing wire (see Figure 11). As seen in Figure 4, stent 10 employs multiple reinforcing wires 19 that spiral from opposing directions creating a diamond-like wire pattern. As seen in Figure 13, a single wire 19 is employed spiraling around the circumference of the stent in a generally angled yet parallel configuration. As seen in Figure 14, multiple wires 19 are employed in a square-wave type pattern. Or, as seen in Figure 15, multiple wires 19 are employed in coil-like patterns. The subject five patterns are not exhaustive of the potential patterns that can be employed in stent 10, but merely depict the preferred embodiment (Figure 3) and four alternate embodiments (Figures 4, 13, 14, and 15) respectively.

Stent 10 of the present invention is made using a knitting machine 20 schematically depicted in Figure 1. It is noted that the preferred stent of the present invention is made with more than one wire strand. Accordingly, Figure 1 is illustrative of the inventive knitting machine used to create one of the alternate stents of the present invention, as seen in Figure 13 - stent 10 having one wire 19. The preferred stent, as in Figure 3, would be made from knitting machine 20 employing two or more wire strands and at least three yarn strands. The ratio of metal strands to textile strands is about 1:2.

As seen in Figure 1, knitting machine 20 includes an intake section 21 receiving strands 23, 25 and 27 of yarn from three respective spools of yarn 29, 31 and 33. Intake section 21 of knitting machine 20 also receives a strand of reinforcing

wire 35 from a spool of wire 37. Spool of wire 37 has a braking mechanism 39 acting thereupon for a reason to be described in greater detail hereinafter. An outtake 41 of the knitting machine 20 is seen to have, emanating therefrom, the knitted stent 10 having fabric portions 17 and the reinforcing wire 19 spiraling therethrough.

In the preferred method of knitting the stent 10, the spool 37 is caused to supply reinforcing wire 35 at a slower supply rate than is the case for the strands 23, 25 and 27. For this purpose, the brake mechanism 39 may be activated to a desired degree of braking force to slow down the supply of wire 35 to a ratio of, for example, 1:4 as compared to the speed of supply of the strands 23, 25 and 27 of yarn.

With reference to Figure 2, a schematic depiction of one of the strands of yarn 25 and the reinforcing metal wire strand 35 is shown with the manner of intertwining of these strands being schematically depicted. As should be understood, per unit inch of stent length, a much lengthier portion of the strand of yarn 25 is woven than is the case with the reinforcing wire strand 35. In the example described above, the strand of yarn 25 could be as much as four times as long as the reinforcing wire strand 35 per unit length of the finished stent 10. As a result of this knitting technique, a stent 10 is woven having a wire strand 35 braided about the yarn portions 17, locking the yarn together and thereby providing a stent with increased radial strength.

In the braiding of wire to textile strand, the wire and textile strand are crossed on top of each other so that the textile is tightly held because of the crossing pattern to produce a stent with low porosity. The crossing pattern determines the appearance of the surface, radial strength of the stent graft and the elasticity in both the radial and longitudinal direction. Elasticity in the longitudinal or axial direction provides a low profile for the stent as it is introduced into a body lumen.

This invention produces a stent that does not have areas of blood leakage, but does provide for passage of ions necessary for proper lumen wall function.

The wire and the textile strand can be introduced into the braid in separate spools or they can be mixed together in one spool and then introduced into the process. Alternatively, the textile strand and a single wire filament each could be braided into a two filament mixture and then fed by several spools to form a braid.

The preferred ratio of wire strand to textile strand is 1:2. The wall thickness of the stent is such that in the compressed state, a double wall thickness is at least one-fifth (1/5) an end diameter of the stent. For example, if the final end diameter of the stent is 6 mm, the compressed double wall thickness is about 1.20 mm.

In the preferred embodiment of the present invention, the strands of yarn 23, 25, 27 may be made of any suitable fabric material such as, for example, polyester, polypropylene, polyethylene, polyurethane, polytetrafluoroethylene or other fabric materials. Such strands of yarn can be monofilament or multi-filament. If monofilament strands are used, the strands can be twisted or wound prior to being fed into the knitting machine 20.

Suitable materials for the reinforcing wire 35 may include Stainless Steel, Tungsten, Titanium, NITINOL, Gold or Silver. Furthermore, in the preferred embodiment, the wire 35 may have a diameter of approximately 0.004 inches and is of a greater thickness than that of the yarn. Wire 19 can be round or flat wire. The number of spools supplying yarn is greater than the number of spools supplying the metal wire. In the preferred embodiment, the ratio of the surface area (fabric to metal) is 7:3, but other ratios can be employed.

As seen in Figures 7 - 12, methods of employment to deliver stent 10 into the body are depicted. As seen in Figures 7 and 8, in a first method of employment, stent 10, in a collapsed state, is wrapped about a first end 42 of a catheter 43 and covered by a sheath 45 at catheter first end 42. A catheter second end 44 distal from catheter first end 42 has a slot 47, formed therealong, enclosing a pull wire 49. After delivering the aforementioned mechanism into the body, pull wire 49 is pulled in a direction away from catheter first

end 42 (Figure 8), thereby removing sheath 45 from stent 10 permitting stent 10 to expand. A stop 51 located at catheter second end 44 prohibits sheath 45 from being pulled completely off and provides a means to remove the delivery mechanism from the body.

As seen in Figures 9 and 10, a second method of employing stent 10 into the body is shown. Therein, stent 10 is wrapped about a first end 42′ of catheter 43′, in a collapsed state, and secured by a wrap wire 45′. Wrap wire 45′ feeds into a slot 47′ formed within a catheter second end 44′. After the aforementioned mechanism has been delivered within the body, wrap wire 45′ is pulled in a direction away from catheter first end 43′ such that wrap wire 45′ unravels stent 10 (Figure 10). Stent 10 is thereby permitted to expand. The delivery mechanism is then removed from the body leaving only the expanded stent within the body.

As seen in Figures 11 and 12, a third method of employment of stent 10 is shown. Therein, stent 10 is again wrapped, in a collapsed state, about a first end 42′′ of a catheter 43′′ and secured by a wrap wire 45′′. Wrap wire 45′′ feeds into a slot 47′′ formed within a catheter second end 44′′. After the aforementioned mechanism has been delivered within the body, wrap wire 45′′ is twisted such that wrap wire 45′′ unravels stent 10 (Figure 12). Stent 10 is thereby permitted to expand. The delivery mechanism is then removed from the body leaving only the expanded stent within the body.

A flat or a round wire is used in the braid, but a flat wire is preferable because it contributes towards optimal wall thickness. The fabric portion provides a barrier similar to an arterial wall to prevent tissue from growing into the stent, but permits transport of ions and other essential elements to and from the arterial wall to the blood.

A preferred configuration of the wire in the braided pattern is that if a "Z" to provide maximum reinforcement of the textile portion.

Accordingly, an invention has been disclosed in terms of a preferred embodiment thereof which fulfills each and every one of the objects of the present invention as set forth

hereinabove and provides a new and useful wire reinforced fabric stent and method of weaving of great novelty and utility.

Of course, various changes, modifications and alterations in the teachings of the present invention may be contemplated by those skilled in the art without departing from the intended spirit and scope thereof.

As such, it is intended that the present invention only be limited by the terms of the appended claims.

Claims

1. A stent characterized by a tubular body having opposed ends, the tubular body made from a fabric material and at least one reinforcing wire interwoven within the fabric material between the opposed ends.

2. The stent of claim 1, wherein the fabric material is woven and is characterized by at least a partial fabric layer.

3. The stent of claim 2, wherein the at least one wire forms at least a partial metal layer.

4. The stent of claim 3, wherein an outer circumference of the tubular body is characterized by alternating fabric layers and integrally woven fabric-metal layers disposed between the tubular body opposed ends.

5. The stent of claim 4, wherein inner metal layers are juxtaposed directly underneath the outer fabric layers.

6. The stent of claim 3, wherein an outer circumference of the tubular body is characterized by alternating fabric layers and metal layers disposed between the tubular body opposed ends.

7. The stent of claim 6, wherein inner metal layers are juxtaposed directly underneath the outer fabric layers and inner fabric layers are juxtaposed directly underneath the outer metal layers.

8. The stent of claim 1, wherein the wire is made of a material chosen from the group consisting of Stainless Steel, Tungsten, Titanium, NITINOL, Gold and Silver.

9. The stent of claim 1, wherein one wire is interwoven within the fabric material in a spiraling pattern.

10. A stent characterized by a tubular body having opposed ends, the tubular body made from a fabric material and a multiplicity of reinforcing wires interwoven within the fabric material between the tubular body opposed ends.

11. The stent of claim 10, wherein the multiplicity of wires are interwoven in a spiraling pattern in a single direction.

12. The stent of claim 10, wherein the multiplicity of wires are interwoven in a spiraling pattern in opposed directions.

13. The stent of claim 10, wherein the multiplicity of wires are interwoven in square-wave like patterns.

14. The stent of claim 10, wherein the multiplicity of wires are interwoven in coil-like patterns.

15. A method of making a stent including the steps of:

a) providing a knitting machine having an intake and an outtake;

b) supplying the intake with a plurality of yarn strands and at least one reinforcing wire strand; and

c) knitting the strands together into a tubular stent while controlling a supply speed of the wire strand to be below a supply speed of the yarn strands whereby a stent is formed having a tubular yarn body with the at least one reinforcing wire interwoven therewithin.

16. The method of claim 15, wherein the supplying step includes the step of providing spools of yarn and wire.

17. The method of claim 15, wherein the plurality of yarn strands is characterized by three strands.

18. The method of claim 15, wherein the controlling step includes the step of braking rotation of the wire spool.

19. The method of claim 18, wherein the braking step causes the wire spool to supply wire to the knitting machine at a supply ratio of about 1:4 as compared to yarn supply.

20. The method of claim 15, wherein the knitting step includes the step of forming a tubular stent with a separate reinforcing wire layer adjacent a yarn layer.

21. A process for making a stent comprising

(a) providing at least one wire strand;

(b) providing a plurality of textile strands;

(c) braiding the wire strands to textile strands at a ration of about 1:2 into a monolayer integrated tubular shape having a double wall thickness at least 1/5 an end diameter of the stent, the tubular shape adapted to have axial and radial compressibility for insertion into a vascular or nonvascular system of the body.

22. The process according to claim 21, wherein the wire strands braided to the textile strands are selected from the group consisting of Stainless Steel, Tungsten, Titanium, NITINOL, Gold and Silver.

23. The process according to claim 21, wherein two wire

strands are provided.

24. The process according to claim 23, wherein the two wire strands are braided to the textile strands that spiral from opposing directions creating a diamond-like wire pattern.

25. The process according to claim 21, wherein the at least one wire strands is a single wire spiraling around the circumference of the stent.

26. The process according to claim 21, wherein the at least one wire strands are multiple wire strands employed in a square-wave like pattern.

27. The process according to claim 21, wherein the at least tne wire strands are employed in coil-like patterns.

28. The process according to claim 21, wherein braiding the wire strands to textile strands is carried out in a knitting machine.

29. The process according to claim 28, wherein an intake section of the knitting machine receives at least three strands of yarn and at least one strand of reinforcing wire.

30. The process according to claim 29, wherein a brake mechanism on a spool supplying the wire causes the spool to supply wire at a slower rate than spools supplying the yarn.

31. The process according to claim 21, wherein the textile strands are selected from the group consisting of polyester, polypropylene, polyethylene, polyurethane and polytetrafluoroethylene.

32. A process according to claim 21, wherein the wire strand is provided with a diameter of about 0.004 inches.

33. The process according to claim 21, wherein the wire strand is flat.

34. The process according to claim 21, wherein the at least one wire strands has a "Z" pattern with respect to the textile portion.

35. A process for making a reinforced stent adapted to have axial and radial compressibility for insertion into a blood vessel, the process characterized by:

(a) providing a knitting machine with an intake portion;

(b) providing multiple textile strands from separate textile spools to the intake portion;

(c) providing at least one wire strand to the intake portion from a wire supply spool; and

(d) braiding the at least one wire strand to the textile strands to form a monolayer integrated tubular shape having a double wall thickness of at least 1/5 an end diameter of the reinforced stent.

36. The process according to claim 35, wherein the wire strand to textile strand ratio is about 1:2.

37. The process according to claim 35, wherein the at least one wire strand are two wire strands.

38. The process according to claim 35, wherein the at least one wire strand has a "Z" pattern with respect to the textile portion.

39. The process according to claim 35, wherein the at least one wire strand is a braided multifilament.

40. The process according to claim 35, wherein the reinforced stent is coated with biological matter selected from the group consisting of anticoagulants and antifibrotic healing agents.

41. The process according to claim 35, wherein the reinforced stent is coated with an antitumor agent selected from the family consisting of taxol and epothilone.

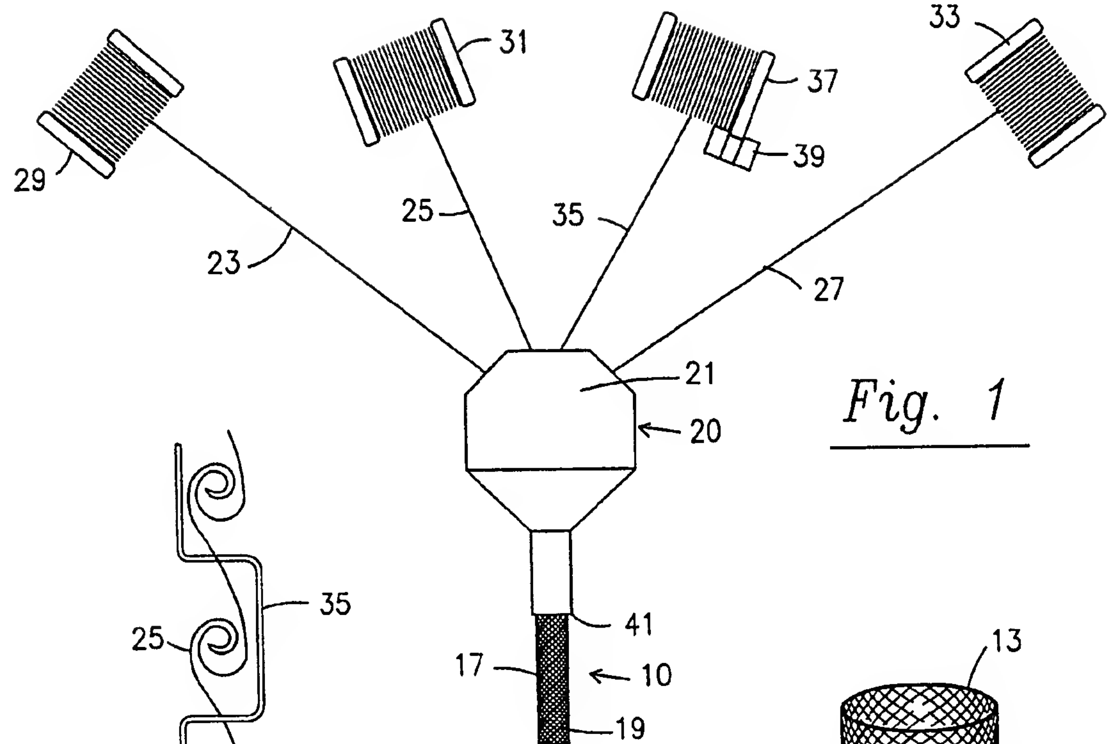

Fig. 1

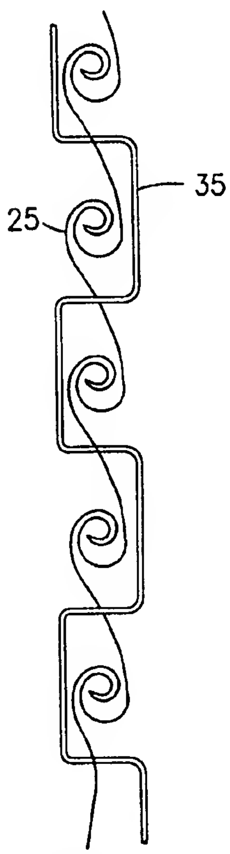

Fig. 2

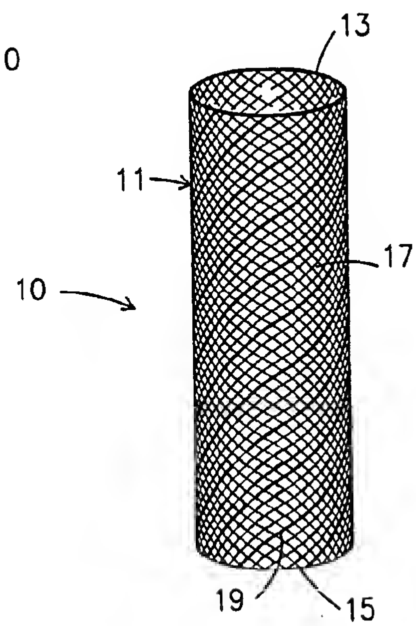

Fig. 3

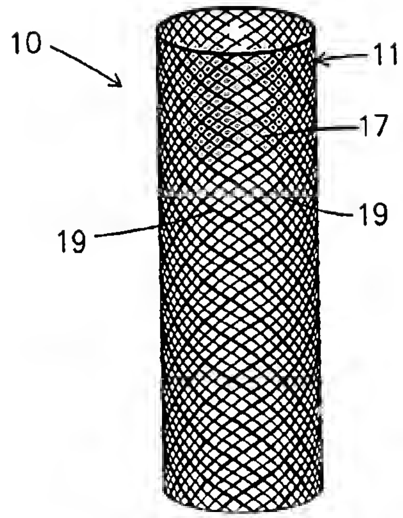

Fig. 4

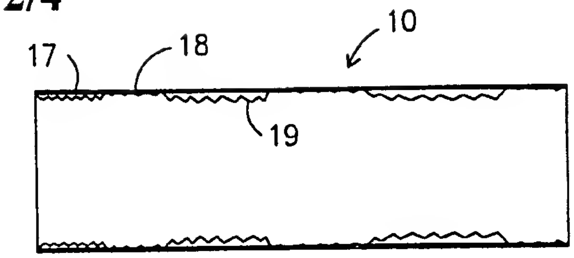

Fig. 5

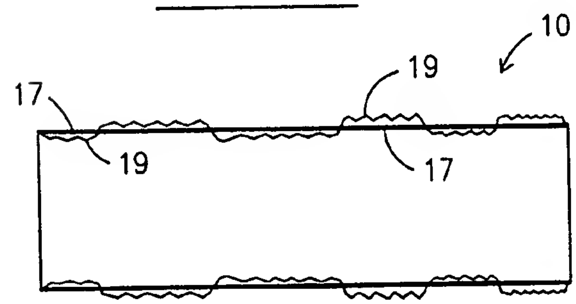

Fig. 6

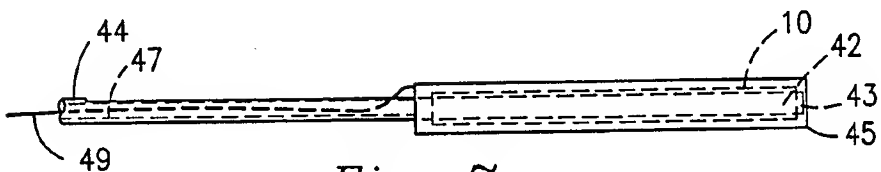

Fig. 7

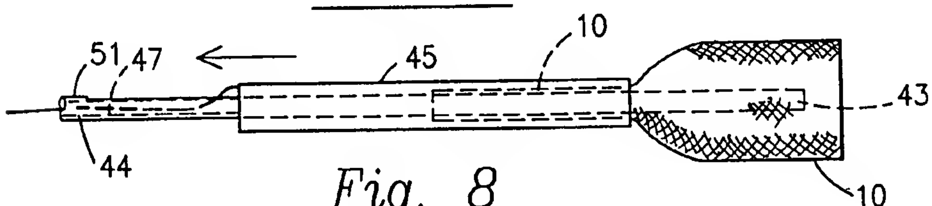

Fig. 8

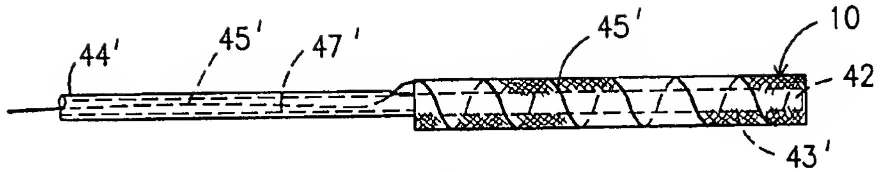

Fig. 9

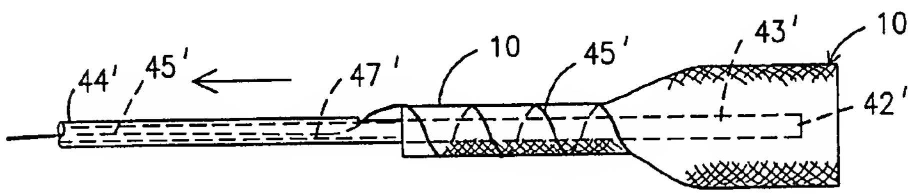

Fig. 10

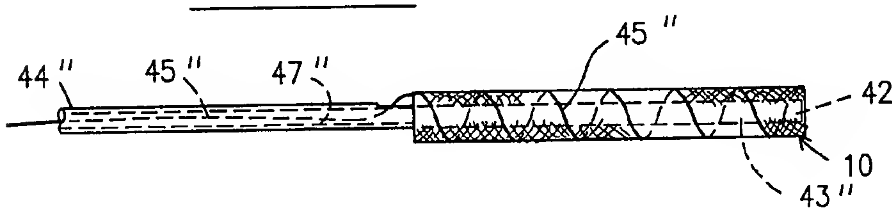

Fig. 11

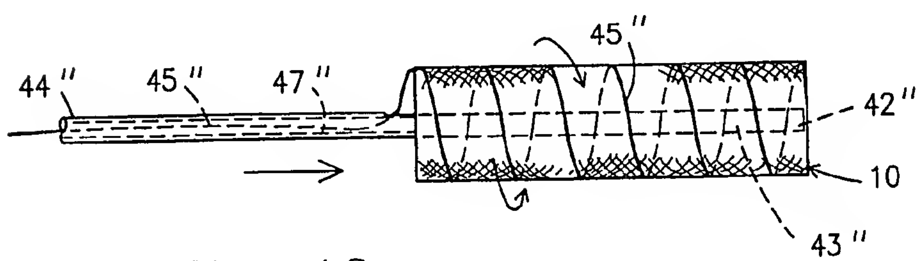

Fig. 12

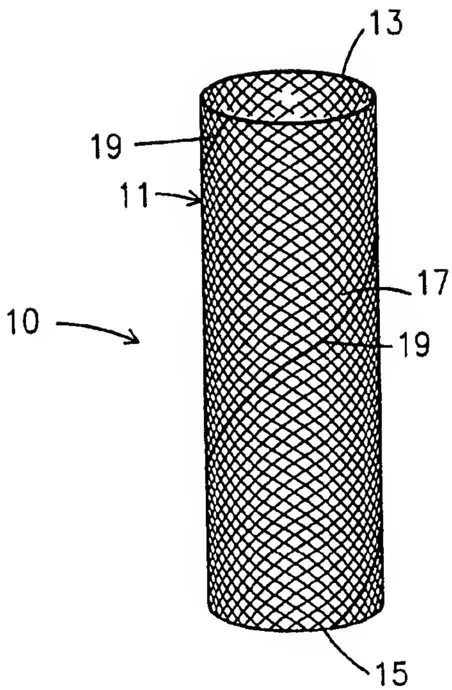

Fig. 13

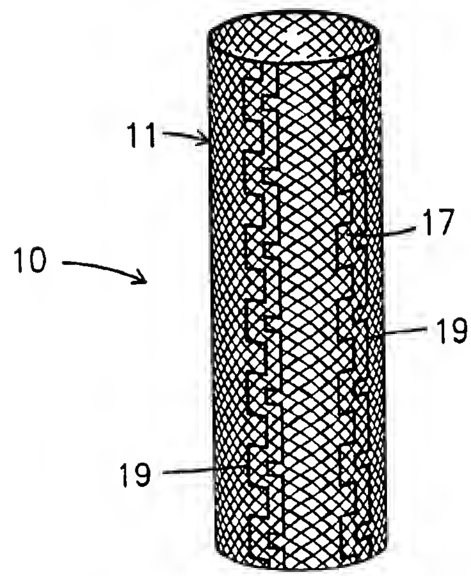

Fig. 14

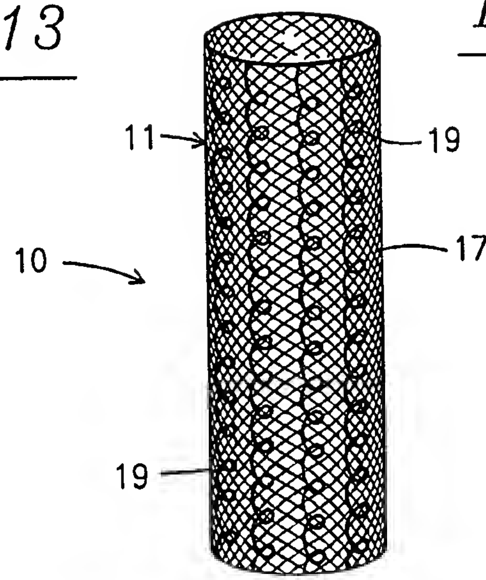

Fig. 15